

## **REMARKS**

The non-final Office Action mailed September 28, 2009, has been received and reviewed. The preceding amendments and the following remarks form a full and complete response thereto. Claims 30-38, 42-43, and 46-57 are currently pending in this application. Claim 30 has been amended to recite that the device includes "a well for holding a liquid having the analyte dissolved or suspended therein in contact with the transducer." Support for this amendment is found in originally filed claims 12 and 13, and on pg. 7, Ins. 7-8 and pg. 13, Ins. 12-15 of the application as filed. Additionally, Claim 30 now recites that "the time delay is no greater than 150 milliseconds." Support for this amendment is found in originally filed claim 9. The preamble of claim 49 has been amended to recite: "[a] method of detecting an analyte dissolved or suspended in a liquid sample, comprising the steps of." Additionally, claim 49 has been amended to recite: "exposing the liquid sample, containing the dissolved or suspended analyte, to a transducer having a pyroelectric or piezoelectric element and electrodes which is capable of transducing a change in energy to an electrical signal." Claim 56 was amended to maintain antecedent basis. Support for these amendments can be found in originally filed claim 12. Claims 39-41 and 44-45 have been cancelled. No new subject matter has been added.

## **Drawings**

The Office Action has objected to the drawings under 37 C.F.R. § 1.83(a)

because the reagent chamber recited in claims 46 and 47 is not shown. By this Amendment a corrected drawing sheet has been submitted. The corrected Fig. 1 shows that the reagent chamber is in communication with the transducer 3. Support for this amendment can be found in the originally filed claims 14 and 17, and at pg. 8, Ins.22-23 of the application as filed. Applicants respectfully request that this objection be withdrawn.

**Claim Rejections under 35 U.S.C. §103**

The Office Action has rejected claims 30-34, 37-38, 42-53, 56 and 57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,622,868 to Clarke et al. (Clarke) in view of U.S. Patent No. 7,244,572 to Schwabacher et al. (Schwabacher). Applicants assert that neither Clarke nor Schwabacher, taken alone or in combination, render the current invention obvious. Applicants now traverse this rejection.

Before addressing the specifics of the current rejection, Applicants now provide some background regarding the present invention. The current invention is an improvement over the prior art in the field for at least the reason that it allows a user to detect a bound analyte in the presence of a bulk solution or a suspension containing unbound analyte. That is, in a liquid sample, an analyte bound near to the surface of the transducer can be distinguished from an analyte dissolved or suspended in the liquid sample. This ability to distinguish between the bound and unbound analytes is described throughout the specification and is accomplished, at least in part, by "depth

profiling." Utilizing the current invention, a number of binding assays, such as immunoassays, to be carried out without waiting for each assay to finish and then washing away the remaining unbound analyte. This significantly improves the efficiency and the utility of such assays.

Clarke is generally directed to an analytical apparatus utilizing a colorimetric or other optically detectable effect. More particularly, Clarke discloses an apparatus for detecting optical effects on the surface of a transducer. See Clarke col. 2, Ins. 16-26, 34-36; col. 3, Ins. 1-9; col. 4, Ins. 25-27. This is the type of prior art already disclosed in and discussed by the current specification at pg. 1, Ins. 13-33. Additionally, Applicants note that the Office Action admits that Clarke does not "disclose that the processor is adapted to measure the delay from the time a pulse of radiation from the light source is generated and a signal from the reagent is detected." See Office Action pg. 4, para. 2.

Schwabacher is generally directed to one-dimensional arrays on optical fibers. More particularly, Schwabacher discloses the use of linear arrays of chemosensors, that are supported by an optical fiber, that can be used to rapidly assay the entire array using changes in the optical properties along the optical fiber. See Schwabacher Abstract. Additionally, Schwabacher discloses that "[t]he individual agents can be identified by their location along the fiber, and the time delay between delivering light and detecting a change in light can be used to determine the location and therefore the identity of the compound." See Schwabacher col. 6, Ins. 14-18.

Clarke fails to disclose: "a detector which is capable of detecting the electrical

signal generated by the transducer, wherein the detector is adapted to determine the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal, and wherein the time delay is no greater than 150 milliseconds,” as is recited in claim 30 (and similarly recited in claim 49). One feature of the present invention is that of depth profiling, namely the ability to distinguish between a bound and unbound analyte in proximity to the transducer. Depth profiling is accomplished, in part, by finding a time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal. In order to measure this precise time delay the detector must be configured to take readings up to a time delay of 150 ms and no more. As noted above, Clarke fails to disclose that the processor is adapted to measure the delay from the time a pulse of radiation from the light source is generated and a signal from the reagent is detected. Thus logically, Clarke fails to disclose that the measured time delay is no greater than 150 milliseconds, as is recited in both pending independent claims.

Schwabacher fails to cure the defects of Clarke. Schwabacher fails to disclose that the measured time delay is no greater than 150 milliseconds, as is recited in both claim 30 and 49. Schwabacher discloses finding the location of individual agents along the fibre in order to identify the compound. See Schwabacher col. 6, Ins. 14-18. Thus logically, the detector of Schwabacher will measure all time delays in order to correlate them to the compound locations on the optical fibre. This is different from the current invention, which claims the measured time delay to no greater than 150 milliseconds in

order to differentiate the bound and the unbound analytes in a solution or sample.

Because Schwabacher fails to cure the above discussed defects of Clarke, independant claims 30 and 49 are patentable over the combination of Clarke and Schwabacher. Because independent claims 30 and 49 are patentable, defendant claims 31-34, 37-38, 42-43, 46-48, 50-53, and 56-57 are likewise patentable. Applicants respectfully request that this rejection be withdrawn.

Additionally, it should be noted that Schwabacher is related to optical fibers, which is different from and not related to the current invention. That is, the system described in Schwabacher is concerned with the measurement of photons. In contrast, the present invention utilizes a pyroelectric /piezoelectric transducer which measures the generation of heat and shock waves from a sample. These are two divergent technical approaches and one skilled in the art would not look to one when seeking to improve the other. One of ordinary skill in the art certainly would have no expectation that he could successfully apply principles from the detection of photons to the detection of a heat/shock wave signals by a pyroelectric/piezoelectric transducer following propagation through the sample medium. Moreover, there would be no expectation of being able to provide a technically meaningful signal from such an experiment. Consequently, one of ordinary skill in the art would not combine Clarke and Schwabacher in order to solve the problem of the present invention, i.e. being the ability to distinguish between bound and unbound analyte utilizing depth profiling in a pyroelectric/piezoelectric transducer system. Thus, the combination Clarke and

Schwabacher suggested by the Office Action is purely impermissible hindsight. For at least this additional reason, claims 30-34, 37-38, 42-53, 56 and 57 are patentable over the combination of Clarke and Schwabacher. Applicants respectfully request that this rejection be withdrawn.

The Office Action has rejected claims 35, 36, 54 and 55 as allegedly being unpatentable over Clarke in view of Schwabacher, and further in view of U.S. Patent No. 6,306,598 to Charych et al. (Charych). The Office Action cites to Charych et al. as allegedly disclosing the use of avidin/biotin conjugate to bind an analyte of interest. However, because Charych fails to cure the deficiencies of both Clarke and Schwabacher, claims 35, 36, 54 and 55 are patentable over the prior art. Applicants respectfully request that this rejection be withdrawn.

In view of the foregoing, all objections and rejections have been sufficiently addressed. The Applicants submit that the application is now in condition for allowance and request that claims 1-5, 9-12, 39, 48, 59, 62-63 and 76 be allowed and this application passed to issue.

In the event that this paper is not timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension together with any additional fees may be charged to Counsel's Deposit Account No. 02 2135.

If for any reason the Examiner determines that the application is not now in condition for allowance, it is respectfully requested that the Examiner contact, by telephone, the Applicants' undersigned attorney at the indicated telephone number to

arrange for an interview to expedite the disposition of this application.

Respectfully submitted,

12/28/2009

Date

/Joseph E. Green/

Attorney for the Applicants

Joseph E. Green

Reg. No. 60,197

ROTHWELL, FIGG, ERNST & MANBECK

1425 K Street, N.W.

Suite 800

Washington, D.C. 20005

(202) 783-6040